

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendments filed on Feb. 18, 2010 have been entered.

### ***Status of the Claims***

Claims 1-11, 13-17, and 19-42 are pending. Claims 1-8, 13, and 14 have been amended; claims 12 and 18 are cancelled; claims 19-28 are withdrawn; claims 41 and 42 have been added. Claims 1-11, 13-17, and 29-42 are now under consideration. This Office Action is in response to the request for continued examination filed on Feb. 18, 2010.

### ***Information Disclosure Statement***

References lined-through on the information disclosure statement(s) were not considered because they were not provided or were not provided in English.

Regarding the reference referred to on p. 14 of the response (New Food Industry Article). This reference was previously indicated as considered in the supplemental IDS mailed to applicants on 12/7/09.

***OBJECTIONS/REJECTIONS WITHDRAWN***

The rejections of claims 12 and 18 are moot in light of the claim cancellations.

***OBJECTIONS/REJECTIONS MAINTAINED***

The rejection of claims 1-11, 13-17, and 29-40 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph is maintained, as discussed below.

The rejection of claims 1-11 and 13-17 under 35 U.S.C. 102(b) over LINA is maintained as discussed below.

The rejection of claims 1-11 and 13-17 under 35 U.S.C. 102(b) over BUCKE is maintained as discussed below.

The rejection of claims 1-11 and 13-17 under 35 U.S.C. 102(e) over BRENDEL is maintained as discussed below.

The rejection of claims 29-40 under 35 U.S.C. 103(a) over LINA and SHIMIZU is maintained as discussed below.

***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> Paragraph) (Maintained)***

**Claims 1-11, 13-17, and 29-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

In claims 1-3, 7, and 8, the recitation, "5 g or more of isomaltulose per 60 kg of body weight of an individual" renders the claims indefinite. Likewise, the recitation "10 g or more of isomaltulose per 60 kg of body weight of an individual" in claims 4-6, 13, and 14 is indefinite. These recitations are analogous to method steps in a product claim since they imply the active step of administering the composition to an individual. However, it is noted that administration is not required by the claims. Administration to an individual is an intended use of the claimed product, which carries no patentable weight. Furthermore, the amounts of isomaltulose (i.e. 5 or 10 g) are linked to a particular body weight of an individual, but administration to a particular individual is not actually required. Thus, the plain meaning of the claim requires different amounts of isomaltulose be administered to individuals of different weights. Since administration to a person is not actually required by the claims, it is not clear how much isomaltulose must be present to meet the claim.

In light of applicants' arguments, the claims will be construed as limiting the amount of isomaltulose in the composition. Due to the issues raised in this indefiniteness rejection, the amount will be construed as 0.083 g/kg (i.e. 5g/60kg) isomaltulose or 0.167 g/kg (10g/60kg) as applicable per the claims, or any amount that could reasonably supply these doses to any subject.

***Response to Arguments***

Applicants' arguments have been fully considered but are not persuasive. Applicants present claims from two U.S. patents, which recite language similar to that used in the present claims and argue that since the issued claims are presumed to be valid, the present claims must therefore be definite (response, p. 18).

It is acknowledged that similar language has been used previously in patent claims and, in some circumstances, may be acceptable. However, each patent application (and each claim therein) is evaluated on its own merits (See MPEP § 2107.02). As such, a comparison with other patent claims is not a valid argument for why the term is enabled in *this case*. Moreover, issued patents are not legal precedent. The examiner has presented a detailed rationale for why the term is *not* definite in the instant case. The limitation in question attempts to limit the amount of isomaltulose in the composition, but in doing so requires that the composition be administered to a hypothetical individual. However, the instant claims are product claims, not method claims, and cannot properly recite such method steps, which, in any case, represent no more than intended use of the claimed composition.

Applicants point to the prior art and an NPL reference showing similar measures of dosages, thus, admitting the obviousness of such a dosing regimen. However, applicants have claimed a composition (i.e. a product), not a method of dosing a compound. The implied method steps render the composition claims indefinite. See MPEP § 2173.05(p), which states that "A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. \*> *IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d

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1140, 1145 (Fed. Cir. 2005);<*Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) \*>(< claim directed to an automatic transmission workstand and the method \* of using it \* held \*\* ambiguous and properly rejected under 35 U.S.C. 112, second paragraph>)<.

Applicants state that the limitation is intended to "normalize" the dose of isomaltulose per individual. However, this necessarily requires that different total amounts of isomaltulose meet the instant claim limitation based on the hypothetical individual to which the dose is hypothetically administered, neither of which are recited in the claim. If applicants intend to limit the amount of isomaltulose in the composition, it can and should be done in such a way as to not require any method step(s) to be performed (i.e. such as selecting an individual and administering to said individual). Again, applicants are attempting to rely on the implied method steps in the claims to show definiteness, when the method steps themselves render the claim indefinite.

***Claim Rejections - 35 USC § 102 (Maintained)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-11 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by LINA (Lina, B. A. R., et al. (2002). Food and Chem. Tox. 40(10); 1375-1381; published online May 2, 2002).**

1. Lina teaches that isomaltulose (i.e. PALATINOSE<sup>®</sup>) is a natural occurring disaccharide that has been used as a sugar in Japan since 1985 (abstract). Lina teaches that isomaltulose is particularly suitable as a non-cariogenic sucrose replacement in products for diabetics, in part because blood glucose levels in humans after oral administration of isomaltulose are attenuated compared to sucrose administration (abstract; p. 1377, left col., 1<sup>st</sup> full paragraph; p. 1379, left col., 2<sup>nd</sup> paragraph). Lina teaches the use of isomaltulose as an alternative sugar in most sweet foods (abstract; p. 1375, right col., middle paragraph). Lina also teaches compositions comprising both isomaltulose and sucrose (i.e. wherein the two compounds are administered simultaneously) (p. 1377, right col., last paragraph). Lina teaches administration of isomaltulose at levels of up to 8.1 g/kg body weight in rats and up to 1 g/kg in humans (p. 1378, right col.). It is noted that the term "carrier" has not been defined in the instant specification. Merriam-Webster defines a carrier as, *inter alia*, a usually inactive accessory substance: vehicle. Thus, the "carrier" of the instant claims can be virtually any substance that acts as a vehicle for isomaltulose. Lina teaches administering isomaltulose in the diet in the form of foods (p. 1377, left col., bottom par., right col., top and bottom pars.; p. 1378, left col., section 3.2, right col., top par.). The diet/foods of Lina meet the language of the instant claims.

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2. It is noted that the "wherein" clauses in claims 1-11 and 13-17 are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an  $\alpha$ -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

3. Additionally, claims 7, 12, and 13 require the presence of a foodstuff composed of a carbohydrate "having an  $\alpha$ -1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides." This recitation embraces carbohydrates having 0% of the recited ratio (i.e. carbohydrates which do not have any  $\alpha$ -1,6-glucosyl bonds). Thus *any* carbohydrate (e.g. sucrose) meets the claim. In addition to sucrose, Lina also teaches replacing part of the starch in foods with isomaltulose (p. 1378, section 3.2) and teaches feeding 10%, 20%, 30%, or up to 56% isomaltulose as part of feed/foodstuffs (p. 1376, right col. 1<sup>st</sup> full par.; p. 1377, bottom of left and right cols.; p. 1378, top of left col.; p. 1379, left col. bottom par.).

4. It is further noted that the ability of isomaltulose to reduce an increase in blood glucose level, or reduce body fat accumulation is an inherent property of the compound. Products of identical chemical composition can not have mutually exclusive properties.

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Thus, any composition comprising isomaltulose would have this property and reads on the claims. Claims 1-9 and 13-15 are anticipated by Lina. Claims 10-11 and 16-17 are also anticipated since they merely present additional "wherein" clauses that recite intended use and are not afforded patentable weight.

### ***Response to Arguments***

Applicants' arguments have been fully considered but are not persuasive. Applicants assert that the MPEP does not support the examiner' position that the instant "wherein" clauses have no patentable weight (response, p. 23-24).

Applicants are incorrect. This position is fully supported by the MPEP. See MPEP § 2111.04. Applicants' inconsistency regarding the case law cited in the MPEP is noted. On one hand, applicants assert that *Hoffer v. Microsoft Corp* (in which process claims were at issue) prohibits the examiner's position. On the other hand, applicants argue that *Minton v. Nat'l Ass'n of Securities Dealers, Inc.* is drawn to method claims and cannot be applied to applicants' composition claims. Thus, for at least these reasons applicants' arguments are unpersuasive.

Applicants argue that the "wherein" clauses should be given patentable weight because they reflect properties of the composition. Applicants further argue that the ability of isomaltulose to reduce an increase in blood glucose level and body fat accumulation is not inherent (response, p. 23-28).

The examiner disagrees. The examiner has considered each and every limitation of the claims, and has properly afforded patentable weight only to those limitations that deserve it. Applicants are reminded that they have elected product claims, not method claims, for prosecution on the merits (see applicants' response to the restriction requirement filed Jun. 23, 2008). MPEP 2106(II)(C) states, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." (emphasis added). The MPEP further provides examples of language that may raise a question as to the limiting effect of the language in a claim. Included among these examples are (A) statements of intended use or field of use and (C) "wherein" clauses. As discussed in the prior Office Action, the instant "wherein" clauses do nothing more than recite the intended use and desired outcome of the use of the claimed product. Being product claims, the intended use of the product is not at issue. As such, these limitations do not state a condition material to patentability and are rightly afforded no patentable weight in the claims. In response to applicants' argument that the "wherein" clauses must be afforded patentable weight, applicants are reminded that, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See also See MPEP § 2106(II)(C): "USPTO personnel should begin claim analysis by identifying and evaluating each claim limitation. For processes, the claim limitations will define steps or

acts to be performed. For products, the claim limitations will define discrete physical structures or materials. Product claims are claims that are directed to either machines, manufactures or compositions of matter." (emphasis added). The instant claim limitations do not define discrete physical structures or materials, and thus are not afforded patentable weight. The "wherein" clauses have no patentable weight.

Regarding applicants' assertion that the claimed properties are not inherent, it is noted that this assertion is inconsistent with applicants' own arguments. For example, on p. 24 of the response, applicants repeatedly state that the "wherein" clauses pertain to how the composition effects the host when metabolized, which is a property of the composition. In this case, the effect the invention according to claims 1-3, 7 and 8 has on blood glucose is a property of the claimed composition. Likewise, the effect the invention according to claims 4-6, 13 and 14 has on body fat accumulation is a property of the claimed composition. Additionally, at p. 47 of the response, applicants conclude from their own data that, "palatinose by itself has the function of a "reducer of blood glucose level increase"". Again, applicants attempt to rely on the implied method steps of the claims (which are not afforded patentable weight) in order to show that the undisputed property is not inherent (see response, p. 26). However, based on applicants' own arguments, it is clear that the biological effects of isomaltulose are merely properties of the composition. The step of administering the composition with certain types of carbohydrates, foodstuffs, or foods is not afforded patentable weight, and is indeed not even required by the claims. Lina teaches an identical composition to that instantly claimed. *In re Spada* establishes the inherency of the biological effects,

which applicants admit are properties of the composition. "Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." See MPEP 2112.01. Additionally, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable." See MPEP § 2113.01(II). As stated in the prior Office Action, applicants' own specification suggests that the claimed properties of isomaltulose are inherent in support of the examiner's position. It is noted that there is nothing in the instant claims regarding how much of a decrease in either the blood glucose level or fat accumulation must occur. Applicant has offered no evidence to the contrary.

Applicants argue that Lina reports that, for rats, ingestion of up to 8.1 g/kg body weight/day of isomaltulose did not affect body fat accumulation (response, p. 27).

Again, applicants' statement is incorrect. Lina teaches that body *weight* was not affected by isomaltulose. Lina says nothing about body *fat*. Applicants' statements to the contrary are inaccurate. Moreover, if applicants' arguments with respect to Lina's teachings were accurate, they would represent evidence that applicants are not enabled for their intended use.

Applicants argue that Lina does not teach the amount of isomaltulose instantly recited in the claims (response, p. 28).

Applicants are incorrect. Applicants admit that,

"...the Lina Article discloses feeding rats up to 8.1 g/kg body weight/day of isomaltulose (Lina Article, at 1378, left col., lines 11-15) and giving humans as little as 0.25 g/kg/dose of oral isomaltulose (Lina Article, at 1378, right col., lines 26-32)." (response, p. 28, top par.)

Even the lowest amount taught by Lina (i.e. 0.25 g/kg body weight, pointed to by applicants) is more than applicants' highest claimed amount of 0.167 g/kg (i.e. 10 g per 60 kg body weight). Thus, applicants' statement that Lina does not teach or suggest, "5 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 1-3, 7 and 8, and "10 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 4-6, 13 and 14 is completely without merit because Lina teaches these amounts, contrary to applicants' incorrect assertion. Thus, applicants' arguments regarding the threshold amount of isomaltulose allegedly required to provide the inherent properties are moot since Lina expressly teaches these amounts.

Furthermore, applicants suggest that so long as the amount of isomaltulose exceeds the minimum dose recited, the properties are present (see par. bridging pgs. 22-23 of the response). Lina teaches the claimed amount(s) of isomaltulose. Thus, the properties of blood glucose reduction and fat accumulation reduction are inherent in Lina's compositions. Thus, even if the properties of isomaltulose recited by applicants can be shown not to be inherent (which applicants have not done), these properties must be present in the prior art compositions by applicants own reasoning.

Applicants argue that the examiner has not shown that Lina satisfies the relationship between (A) and (B) of claims 7 and 13 (response, p. 28-29).

Applicants' assertion is incorrect. Applicants are reminded of Lina's teachings and the tremendous breadth of the claims: Claims 7 and 13 require the presence of a foodstuff composed of a carbohydrate "having an  $\alpha$ -1,6-glucosyl bond ratio from 0% to

less than 50% relative to the total bonds among the constituent saccharides." This recitation embraces carbohydrates having 0% of the recited ratio (i.e. carbohydrates which do not have any  $\alpha$ -1,6-glucosyl bonds). Thus any carbohydrate (e.g. sucrose) meets the claim. In addition to sucrose, Lina also teaches replacing part of the starch in foods with isomaltulose (p. 1378, section 3.2) and teaches feeding 10%, 20%, 30%, or up to 56% isomaltulose as part of feed/foodstuffs (p. 1376, right col. 1<sup>st</sup> full par.; p. 1377, bottom of left and right cols.; p. 1378, top of left col.; p. 1379, left col. bottom par.).

**Claims 1-11 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by BUCKE (U.S. 4,587,119; Issued May 6, 1986).**

5. Bucke discloses the use of isomaltulose as a whole or partial replacement for sucrose in food products for human or animal consumption (abstract). Bucke teaches the use of isomaltulose in premixes, such as cake mixes and in beverages (col. 2, lines 4-14; col. 4, lines 32-39). Furthermore, Bucke discloses several embodiments in which the food material comprises an isomaltulose weight ratio of 10% or more relative to the total weight of the carbohydrate in the food material (e.g. Examples 1, 3, 4, 5, and 7). Any of these examples provide the instantly claimed amounts of isomaltulose. The various ingredients of Bucke meet the language of the instant claims regarding a carrier. Bucke anticipates claims 1-11 and 13-17.

6. It is noted that the "wherein" clauses in the claims are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an  $\alpha$ -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds

among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

7. Additionally, claims 7 and 13 require the presence of a carbohydrate "having an  $\alpha$ -1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides." This recitation embraces carbohydrates having 0% of the recited ratio (i.e. carbohydrates which do not have any  $\alpha$ -1,6-glucosyl bonds). Thus any carbohydrate (e.g. sucrose) meets the claim.

### ***Response to Arguments***

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the "wherein" clauses should be given patentable weight (response, p. 32). Applicants argue that Bucke does not teach the claimed amount (i.e. dose) of isomaltulose (response, p. 34).

Applicants' arguments were addressed *supra* in conjunction with Lina, and that discussion is incorporated herein. The "wherein" clauses do not receive patentable weight. At p. 34, applicants have asserted that the examiner has failed to acknowledge or address the amount of isomaltulose taught by Bucke. This is completely incorrect. On p. 9 of the prior Office Action, the examiner stated: "Bucke discloses several embodiments in which the food material comprises an isomaltulose weight ratio of 10%

or more relative to the total weight of the carbohydrate in the food material (e.g. Examples 1, 3, 4, 5, and 7). Any of these examples provide the instantly claimed amounts of isomaltulose." Applicants are reminded of the indefiniteness of the claims and how the amount was construed (see pgs. 16-17 of the prior Office Action). Ingestion of any of the examples of Bucke by, for example, a 50 kg individual meets the claim.

Applicants argue that the examiner has not shown that Bucke satisfies the relationship between (A) and (B) of claims 7 and 13 (response, p. 34-35).

This argument has been addressed *supra*, in conjunction with Lina and that discussion is incorporated herein. Bucke teaches compositions that meet all the structural limitations of the claims.

**Claims 1-11 and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by BRENDEL (U.S. 2002/0192344; Filed Mar. 29, 2002).**

8. Brendel discloses processes for preparing food products with reduced calorific value by replacing the high-calorie substances in the food produces with related substances of reduced calorific value (abstract). Brendel teaches the use of isomaltulose as a replacement for sugars in food products such as biscuits (pars. [0026] and [0030]-[0032]; claim 9). Brendel teaches the use of isomaltulose along with maltodextrins and/or starches such as wheat flour (i.e. carbohydrates having an  $\alpha$ -1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides as defined in par. [0062] of the instant specification). Brendel teaches that isomaltulose may comprise 0.5-98% by weight (relative to the total weight

of the foodstuff, which represents a weight ratio of at least 10% or more relative to the carbohydrate contained in the food (pars. [0026] and [0030]-[0032]; claim 9; Examples 1, 4 and 6). Any of these examples provide the instantly claimed amounts of isomaltulose. The various ingredients of Brendel meet the language of the instant claims regarding a carrier. Brendel anticipates claims 1-11 and 13-17.

9. It is noted that the "wherein" clauses in claims 1-11 and 13-17 are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an  $\alpha$ -1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

### ***Response to Arguments***

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the "wherein" clauses should be given patentable weight (response, p. 38). Applicants argue that Brendel does not teach the claimed amount (i.e. dose) of isomaltulose (response, p. 34).

Applicants' arguments were addressed *supra* in conjunction with Lina, and that discussion is incorporated herein. The "wherein" clauses do not receive patentable

weight. At p. 40, applicants have asserted that the examiner has failed to acknowledge or address the amount of isomaltulose taught by Brendel. This is completely incorrect. On p. 11 of the prior Office Action, the examiner stated: "Brendel teaches that isomaltulose may comprise 0.5-98% by weight (relative to the total weight of the foodstuff, which represents a weight ratio of at least 10% or more relative to the carbohydrate contained in the food (pars. [0026] and [0030]-[0032]; claim 9; Examples 1, 4 and 6). Any of these examples provide the instantly claimed amounts of isomaltulose." Applicants are reminded of the indefiniteness of the claims and how the amount was construed (see pgs. 16-17 of the prior Office Action). Ingestion of any of the examples of Brendel by, for example, a 50 kg individual meets the claim.

Applicants argue that the examiner has not shown that Brendel satisfies the relationship between (A) and (B) of claims 7 and 13 (response, p. 34-35).

This argument has been addressed *supra*, in conjunction with Lina and that discussion is incorporated herein. Brendel teaches compositions that meet all the structural limitations of the claims.

#### ***Claim Rejections - 35 USC § 103 (Maintained)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-6 and 29-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina in view of SHIMIZU (U.S. 2003/0180432; Filed Feb. 6, 2003).**

10. The teachings of Lina are presented *supra*. Lina does not explicitly teach the inclusion of gums or vitamins in the compositions. However, Lina clearly describes the use of isomaltulose as a substitute for various sugars in foodstuffs, for example for diabetics and prediabetics (abstract; p. 1375, right col., last sentence of middle par.; p. 1376, left col., top par.). Since Lina teaches the use of isomaltulose in foodstuffs, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the

invention to include components typically found in edible compositions, such as gums and/or vitamins.

11. For example, Shimizu discloses prepared soymilks and soymilk beverages containing palatinose (abstract; pars. [0010] and [0017]). Shimizu teaches that the compositions can comprise food additives such as gums and vitamins (par. [0022]). The artisan would be motivated to add gums and/or vitamins based on the form of the foodstuff being produced. Thus if an artisan wanted to prepare a soymilk product, it would be no more than routine to add typical food additives such as gums and vitamins to the composition to adjust the desired organoleptic properties of the final food product. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add gums and/or vitamins, to isomaltulose-containing foodstuffs per the teachings of Lina and Shimizu to provide a suitable dietary product.

### ***Response to Arguments***

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Shimizu is not valid prior art (response, p. 43).

Applicants argue that the instant application should be afforded the date of 11/18/02 by virtue of the claim to foreign priority for JP 2002-334032. However, the earliest effective U.S. filing date afforded the instant claims has been determined to be Nov. 18, 2003, the filing date of the instant application.

Acknowledgment is made of applicants' claim to foreign priority under 35 U.S.C. 119(a)-(d). An English language translation of JP 2002334032 was filed with the

USPTO on Jul. 30, 2009. The filing date of the priority document is not perfected unless applicant has filed a certified priority document in the application (and an English language translation, if the document is not in English) (see 37 CFR 1.55(a)(3)) and the examiner has established that the priority document satisfies the enablement and description requirements of 35 U.S.C. 112, first paragraph. In this case, JP 2002334032 does not provide proper support for the instant claims in the manner specified by U.S.C. 112, first paragraph. For example, JP 2002334032 provides no support for the instantly claimed amounts of isomaltulose per kg body weight of an individual. Thus, the full scope of the claims is not supported by JP 2002334032 and the instant claims cannot be afforded the benefit of this foreign priority document. Shimizu stands as valid prior art.

Applicants argue unexpected results (response, p. 45-48).

Applicants' assertion of unexpected results is not persuasive for the reasons of record as set forth in the Office Action dated 11/18/09 (see pgs. 15-16).

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the

absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

***NEW GROUNDS OF OBJECTION/REJECTION***

**Claims 1-11, 13-17, 30, 32, 34, 36, 38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina in view of TAKAZOE (U.S. 4,556,429; Issued Dec. 3, 1985).**

12. The teachings of Lina are presented *supra*. Lina does not explicitly teach the use of the recited sweeteners. However, Lina clearly describes the use of isomaltulose as a substitute for various sugars in foodstuffs, for example for diabetics and prediabetics (abstract; p. 1375, right col., last sentence of middle par.; p. 1376, left col., top par.). Since Lina teaches the use of isomaltulose in foodstuffs, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include components typically found in edible compositions, such as gums and/or vitamins.

13. Takazoe discloses low calorie sweeteners prepared by adding palatinose to sucrose (title; abstract). Takazoe exemplifies compositions comprising vitamin C (Example 3). The skilled artisan would have been motivated to add a vitamin to the composition to increase consumer appeal and/or to take advantage of the well-known antioxidant effects of vitamin C.

**Claims 1-11, 13-17, 29, 31, 33, 35, 37, 39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina in view of BATEMAN (WO 98/04156; Published Feb. 5, 1998).**

14. The teachings of Lina are presented *supra*. Lina does not explicitly teach the use of the recited sweeteners or gums. However, Lina clearly describes the use of isomaltulose as a substitute for various sugars in foodstuffs, for example for diabetics and prediabetics (abstract; p. 1375, right col., last sentence of middle par.; p. 1376, left col., top par.). Since Lina teaches the use of isomaltulose in foodstuffs, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include components typically found in edible compositions, such as gums and/or high-intensity sweeteners.

15. Bateman discloses sugar substitute compositions for table top, baking, and cooking applications (title; abstract). The compositions comprise isomaltulose (p. 28, lines 7-15; claim 3). Bateman teaches the use of intense sweeteners, and teaches that formulation with intense sweeteners helps make some of these more stable in use with colors, fruit juices, and other gums (p. 5, line 20 to p. 6, line 4). Bateman teaches the use of intense sweeteners such as aspartame, acesulfame K, and Arabic gum (p. 2, lines 21-22; claim 2). The skilled artisan would have been motivated to use high-intensity sweeteners and/or gums in the composition to increase consumer appeal and/or to take advantage of the well-known stabilizing effects and or binder/flavor properties of these substances as taught by Bateman. Lina and Bateman render claims 1-11, 13-17, 29, 31, 33, 35, 37, 39, 41, and 42 obvious.

**Claims 1-7, 13, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina in view of Brendel.**

16. The teachings of Lina and Brendel are presented *supra*. Lina does not explicitly teach the use of the recited sweeteners. However, Lina clearly describes the use of isomaltulose as a substitute for various sugars in foodstuffs, for example for diabetics and prediabetics (abstract; p. 1375, right col., last sentence of middle par.; p. 1376, left col., top par.). Since Lina teaches the use of isomaltulose in foodstuffs, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include components typically found in edible compositions, such as gums and/or vitamins.

17. For example, Brendel teaches the use of isomaltulose as a replacement for sugars in food products such as biscuits (pars. [0026] and [0030]-[0032]; claim 9). Brendel teaches that it is also possible to add an intense sweetener selected from the group consisting of, for example, aspartame and acesulfam K. Thus, the artisan would be motivated to add intense sweeteners based on the desired sweetness of the final foodstuff being produced. It would be no more than routine to add typical food additives such high-intensity sweeteners to adjust the desired sweetness properties of the final food product. An artisan would have a high expectation of success in doing so to reduce the overall caloric content of the food product, while maintaining or increasing the sweetness of the food. Claims 1, 13, 41, and 42 are rendered obvious by Lina and Brendel.

***Conclusion***

Claims 1-11, 13-17, and 29-42 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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